510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: K041561

B. Purpose For Submission:

Premarket Notification 510(k) of intention to manufacture and market the Bio-Rad Laboratories Liquichek Whole Blood Volatiles Control.

C. Analyte:

Contains the following analytes: Acetone, Ethanol, Isopropanol, Lead, and Methanol.

D. Type of Test: Validation control material.

E. Applicant: Bio-Rad Laboratories.

F. Proprietary and Established Names:

Bio-Rad Laboratories Liquichek Whole Blood Volatiles Control.

G. Regulatory Information:

1. Regulation section: 21 CFR §862.3280, Clinical toxicology control material.

2. Classification: Class I

3. Product Code: DIF

4. Panel: 91

H. Intended Use:

1. Intended use(s):

   The Liquichek Whole Blood Volatiles Control is intended for use as a quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

2. Indication(s) for use:

   The Liquichek Whole Blood Volatiles Control is intended for use as a quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

3. Special condition for use statement(s): For Prescription Use.

4. Special instrument Requirements:

The intended instruments are stated in the package insert. Values are listed for the intended analyzers.

I. Device Description:

The product is prepared from human blood with chemicals and preservatives added. The control is provided in liquid form for convenience.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Laboratories Whole Blood Tox Control.

2. Predicate K number(s): (K821975A)

3. Comparison with Predicate:

Liquichek Whole Blood Volatiles Control claims substantial equivalence to Whole Blood Tox Control currently in commercial distribution (K821975A). The table below lists the similarities and differences between the Predicate and Proposed device.

Characteristics	**Bio-Rad Laboratories Liquichek Whole Blood Volatiles Control (New Device)**	**Bio-Rad Laboratories Whole Blood Tox Control (Predicate Device K821975A)**
Similarities		
Intended Use	Liquichek Whole Blood Volatiles Control is intended for use as a quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Use Whole Blood Tox quality control material, to monitor the precision of whole blood toxicology test procedures.
Form	Liquid	Liquid
Matrix	Whole Blood	Whole Blood
Preservatives	Contains preservatives	Contains preservatives
Storage (Unopened)	2 °C to 8 °C Until expiration date.	2 °C to 8 °C Until expiration date.
Open Vial	5 days at 2 °C to 8 °C	5 days at 2 °C to 8 °C

Characteristics	**Bio-Rad Laboratories Liquichek Whole Blood Volatiles Control (New Device)**	**Bio-Rad Laboratories Whole Blood Tox Control (Predicate Device K821975A)**
Differences		
Analytes	Contains the following analytes: • Acetone • Ethanol • Isopropanol • Lead • Methanol Does not contain: • Phenylalanine	Contains the following analytes: • Ethanol • Isopropanol • Lead • Methanol • Phenylalanine Does not contain: • Acetone

K. Standard/Guidance Document Referenced (if applicable):

None referenced.

L. Test Principle: Not Applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The mean values printed in the package insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control. Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

b. Linearity/assay reportable range:

Not applicable

c. Traceability (controls, calibrators, or method):

No information was provided about traceability.

The mean values printed in the package insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the reagent manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control.

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek Whole Blood Volatile Control. Product claims are as follows:

1.1 Open Vial Stability: 5 days at 2 to 8 °C.
1.2 Shelf Life: 2 years at 2 to 8 °C.

Real time studies will be ongoing to support the shelf life of this product. All supporting data is retained on file at Bio-Rad Laboratories.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:
   a. Method comparison with predicate device:

   Not applicable

   b. Matrix comparison:

   Not applicable

3. Clinical studies:
   a. Clinical sensitivity:

   Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a and b are not applicable):

Not applicable

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range:

   Not applicable

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.